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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,715	03/14/2001	Theodore S. Jardetzky	AL-8	5680

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HESKA CORPORATION  
INTELLECTUAL PROPERTY DEPT.  
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FORT COLLINS, CO 80525

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/809,715

Applicant(s)

JARDETZKY ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7/12/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/19/01 (4 pages)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Originally filed claims 1-22 have been cancelled. Claims 23-27 directed to elected Group III (original claim 6) have been newly introduced.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26 and 28-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 24-26 and 28-44 are newly introduced claims. Applicant has pointed to various portions of the specification for basis; however, this basis is not agreed with.

At least claims 24-25, 33 and 39 recite “computational means.” The specification does not appear to disclose this generic concept nor what was intended to be embraced by this concept.

At least claims 26, 34, and 41 require obtaining or synthesizing the compound and testing the compound in a binding assay. No method is disclosed as having these steps. The disclosure pointed to on page 146 does not contemplate experimental binding assay steps. This disclosure is clearly in silico.

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At least claims 28, 36, and 42 recite “at least about 95%.” A disclosure of “80% amino acid sequence homology” is not basis nor contemplation for this particular percentage. A fair reading of the specification would not have conveyed to one of ordinary skill in the art that 95 % was particularly preferred or of interest. Furthermore, there is no contemplation in the specification of a method requiring producing a crystal from a complex with the cited sequence characteristics and having the stated spacegroup characteristics. That is, there is no contemplation of the combination of elements recited in the claim. Applicant may not combine different parts of the disclosure to define a new method that was not contemplated.

At least claims 32-33 and 40 recite “performing structure-based design.” The specification does not appear to disclose this generic concept nor what was intended to be embraced by this concept.

Claims 28-30, 36, 38, 42 define the first three-dimensional model by obtaining atomic coordinates following crystallization. There is no basis for such a generic concept. The specification does not disclose nor contemplate producing models having a root mean square deviation of less than 10 angstroms from the coordinates in Table 1 by such crystallization methods. While the particular coordinates in Table 1 may have been found this way, the first model of the claims is not limited to this and the specification does not contemplate designing models that meet these criteria from crystals produced by the recited methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 23-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “interact” and “interaction.” The specification provides no clear definition of what is intended by these terms and there does not appear to be an art understood definition for these terms. That is, it is not known what would be required to meet this claim limitation.

Claim 32 is confusing in that it requires constructing a model in (a); however, this model is not used in (b).

Claim 37 lacks antecedent basis in claim 32 for “said first protein” and “said second protein.”

Claim 39 is confusing in that it requires constructing a model in (a); however, this model is not used in (b).

Claim 40 lacks antecedent basis in claim 39 for “said structure-based design step.”

Claim 43 lacks antecedent basis in claim 39 for “said first protein” and “said second protein.”

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-25, 27, 32-33, 35, 37, 39-40, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freimuth (US 2003/0027338 A1).

Table 1 represents the atomic coordinates determined for a particular crystal structure. This crystal structure is a complex between PhFcεRIα<sub>1-176mut</sub> (SEQ ID NO: 4) and PhFc- Cε3/Cε4<sub>1-222</sub> (SEQ ID NO: 6). As such, the model constructed represents these two proteins complexed (bound) together.

Freimuth discloses using atomic coordinated determined for a crystal structure which is a complex between adenovirus bound to the cellular receptor CAR. This model is used to design or select inhibitors. The inhibitors may be designed de novo or from a known inhibitor. (See at least abstract.)

The difference between the prior art and the claimed invention is the recited three dimensional structure information. This information is descriptive information stored on or employed by a machine. This information is fed into a known algorithm whose purpose is to compare or modify those data using a series of processing steps that do not impose a change in the processing steps and are thus nonfunctional descriptive material. The claimed invention uses

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known software to solve a known problem in a conventional manner. The instant specification acknowledges known prior art computer modeling techniques. Neither the specification nor the claims set forth any special, non-obvious modifications to the known, conventional software and method steps. A method of using a known comparator (e.g. computer modeling techniques known in the prior art to Freimuth for studying complexes) for its known purpose to compare data sets does not become nonobvious merely because new data becomes available for analysis. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. See *In re Gulack*, 703 F. 2d 1381, 1385 (Fed. Cir. 1983) and MPEP 2106. Applicant is also directed to the Trilateral Project WM4 Report on Comparative Study on Protein 3-dimensional (3-D) Structure Related Claims at [http://www.uspto.gov/web/tws/wm4/wm4\\_3d\\_report.htm](http://www.uspto.gov/web/tws/wm4/wm4_3d_report.htm).

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Marianne P. Allen*

Marianne P. Allen  
Primary Examiner

9/16/04

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